REMARKS

In an Office action dated February 1, 2007, Claims 1-6, 9-14 and 16 were finally rejected in view of US Pats. 5,191,885 (Bilof et al.), 4,476,872 (Perlin), 4,640,298 (Pless et al.) and 5,588,432 (Crowley). Claim 1 has been amended to more clearly define the present invention. Claims 4 and 11 have been canceled.

The system of the present invention enables a cardiac arrhythmia to be treated with a probe located in the esophagus. The probe is a transesophageal ultrasonic imaging probe which is covered by a disposable sheath made of a flexible membrane material which is sized to slidably cover the transesophageal portion of the ultrasonic imaging probe and contains an integral stimulation electrode. A physician can use the ultrasonic imaging capability to image the chambers of the heart through the sheath and look for blood clots in a chamber of the heart. The flexible membrane material is thin enough so that it does not significantly enlarge the size of the ultrasound probe and make it more uncomfortable for a patient to swallow. The sheath provides a smooth cover that does not unduly irritate the esophagus. Since the sheath is sized to slide over the ultrasound probe and is make of a flexible membrane which can be very thin, ultrasound transmission and echo reception through the sheath can be accomplished with little or no reverberation artifacts. If no hazardous blood clots are found during imaging, the electrode can be energized to provide electrotherapy to the region of the heart which was imaged. Immediately after the electrotherapy treatment, the heart can be imaged again to look for blood clots or other pathology. After the procedure the sheath-covered probe is withdrawn from the patient's throat, the sheath is removed from the ultrasound probe and disposed of properly. Amended Claim 1 highlights these features of the claimed system.

Bilof et al. propose a laminate electrode structure which can be wrapped around the endoscopic portion of a probe and attach adhesively. After the procedure the structure is peeled off of the probe and disposed of. But Fig. 7 shows the sharp corners and seams of the adhesively attached structure that will be present on the outside of the probe, irritating and potentially injuring the soft tissue of the esophagus. The smooth sheath of the present invention which completely covers the endoscope (see Fig. 1) eliminates the hazards to the patient that Bilof et al. present.

Perlin describes a plastic sleeve 16 in which a monitoring probe is located. A microphone or hydrophone 52 is located at the end of the monitoring probe. No imaging is involved, and the gap seen in Figs 2 and 5 between the microphone and the inner wall of the sleeve and the thick sleeve would cause reverberation artifacts, making imaging through the sleeve difficult if not impossible.

Pless et al. describe an electrical stimulation probe with inflatable balloons. The body of the probe is formed by a polymeric sheath 3 which encloses air passages 2 to the balloons and electrical leads 2 to the outer electrodes. The electrical stimulation is done blindly since the probe provides no imaging capability.

Crowley describes an intravascular imaging catheter which is to be inserted into an extruded polyethylene sheath 12c. The sheath and catheter are then threaded into a chamber of the heart from the femoral artery. The sheath must be relatively rigid and only loosely surround the imaging catheter so that the imaging catheter can be moved longitudinally inside while searching for a therapeutic site in the heart. Since only a loose fit is provided, the sheath must be prepared before use in a filling procedure (bottom column 8) to fill it with fluid through which ultrasound can travel. Without the fluid path, there can

be no ultrasound transmission and reception. By contrast, the sheath of the present invention is sized to snugly cover the outside of the ultrasound probe during use with no movement between the sheath and the probe. The thin flexible membrane causes little or no reverberation to ultrasound and the snug fit of the flexible membrane provides a good acoustic path between the outer covering of the probe and the sheath, aided by gel if desired, and thus no fluid-filling procedure is needed.

For these reasons it is respectfully submitted that amended Claims 1-3, 5-6, 9-10, 12-14 and 16 are patentable over the newly cited references. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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